A single center, open-label Phase 1 trial to evaluate the mass balance and metabolite profile of a single oral dose of pritelivir.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50254

Source
ToetsingOnline

Brief title
Mass balance and metabolite profile of pritelivir.

Condition

- Other condition

Synonym
Herpes

Health condition

Herpes simplex virus (HSV)

Research involving

Human

Sponsors and support

Primary sponsor: AiCuris Anti-infective Cures AG
Source(s) of monetary or material Support: Pharmaceutical Industry.

Intervention

Keyword: Herpes simplex virus (HSV), Pritelivir

Outcome measures

Primary outcome

To evaluate the mass balance of pritelivir, to profile and identify pritelivir

metabolites in plasma and excreta (urine, feces) and to identify

the routes of elimination of pritelivir in humans.

To evaluate pharmacokinetics of pritelivir, AIC090015, AIC090105 and total

radioactivity in plasma and blood and AIC090015 acyl glucuronide

(AIC255698) in plasma only.

To evaluate the blood/plasma ratios for total radioactivity, pritelivir,

AIC090015 and AIC090105.

To obtain additional information on the safety and tolerability of pritelivir.

Secondary outcome

Not applicable.

Study description

Background summary

Pritelivir is a new compound that may potentially be used for the treatment of skin infections caused by viruses such as herpes simplex virus (HSV). Infections with HSV are lifelong, with frequent and sometimes painful recurrences, and carry the risk of serious complications in patients with a weak immune system. Pritelivir can inhibit the replication of HSV and can protect uninfected cells. It is being developed to treat patients with weak immune systems where other treatments of HSV do not work.

Study objective

In this study we will investigate how quickly and to what extend the study compound pritelivir is absorbed, transported, and eliminated from the body). Pritelivir is radioactively labelled with a very small dose of carbon-14 (14C). In this way pritelivir can be traced in blood, urine, and feces. In addition, we will also look at breakdown products of pritelivir.

We also investigate how safe the pritelivir is and how well it is tolerated when it is used by healthy male participants.

We also look at the effect of your genetic information on your body*s response to pritelivir. This part of the study is mandatory.

Pritelivir has been used before by healthy volunteers and patients with herpes simplex virus infection. In addition, it has been extensively tested in the laboratory and on animals.

Study design

The study lasts a maximum of 9 weeks from the inspection to the follow-up check.

For the research it is necessary to stay in the research center for 28 days (27 nights). This is followed by a follow-up visit.

Day 1 is the day on which one receives the research drug. We expect the volunteer at the study center the day prior to the administration of the study drug. You must then report at approximately 12:00 noon. The entry time can be adjusted. If this happens, you will be informed in advance. The volunteer leaves the study center on Day 27 of the study.

Pritelivir is given as capsules containing 240 milliliters (ml) of tap water. The test drug is given while sitting. After ingestion, the volunteer must lie

on his back for 4 hours. During this time, one should not watch/play exciting movies/TV shows or video games.

After taking the study drug, one of the researchers will inspect the hands and mouth. This is to check whether the study drug has been taken. One dose of 100 mg pritelivir is given, containing a very small dose of 14C radiolabelled pritelivir.

Intervention

Not applicable.

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment of the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, seating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take not more than 500 milliliters (mL) of blood from you. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time. If the investigator thinks it is necessary for the safety of a participant, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

Heart tracing
To make a heart tracing, electrodes will be placed on your arms, chest and legs. Prolonged use of these electrodes can cause skin irritation.

Fasting
If you have to fast for a prolonged time during the study, this may lead to symptoms such as dizziness, headache, stomach upset, or fainting.

Coronavirus test
Samples for the coronavirus test will be taken from the back of the nose and throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause the volunteer to gag. When the sample is taken from the back of the nose, they may experience a stinging sensation and the eyes may become watery.

Contacts

Public
AiCuris Anti-infective Cures AG

Friedrich-Ebert-Strasse 475
Wuppertal 42117
DE
Scientific
AiCuris Anti-infective Cures AG

Friedrich-Ebert-Strasse 475
Wuppertal 42117
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Subject has been informed both verbally and in writing about the objectives of the clinical trial, the methods, the anticipated potential risks and the discomfort to which he may be exposed and has given written consent to participation in the trial prior to trial start and any trial-related procedure.
2. Male subjects of any ethnic origin aged between 18 and 55 years (inclusive). Assessed as otherwise healthy based on pre-trial examinations including medical history, physical examination, blood pressure, pulse rate, body temperature, ECG assessment, and clinical laboratory results.
3. Subjects not planning to father or to donate sperms for in vitro fertilization during three months after dosing of trial medication. Adequate contraception must be used during sexual intercourse with women of childbearing potential to make sure the fathering of a child will be ruled out during the trial and during the three months after dosing of trial

medication. Adequate contraception is defined as a combination of a highly effective method of birth control and additional barrier contraception. Highly effective method of birth control is defined as follows: combined (estrogen and progesterone) oral contraceptives, combined hormonal vaginal rings, hormone implants, hormone injectables, or intrauterine device that need to be in place for a period of at least 2 months prior to screening. Additional barrier contraception (the following methods are allowed: condom of the male, diaphragm with spermicide, portio cap with spermicide) must be used for the duration of the trial, defined as from the time of screening to the end of trial examination, and for at least three full months after dosing of trial medication.

Exclusion criteria

1. History or current evidence of clinically relevant allergies or idiosyncrasy to drugs or food.
2. History of allergic reactions to pritelivir or the capsule material (hydroxypropyl methyl cellulose [HPMC]).
3. History or current evidence of any clinically relevant cardiovascular, pulmonary, hepatic, renal, gastrointestinal, hematological, endocrinological, metabolic, neurological, psychiatric, or other disease suspected to influence pharmacokinetics or safety of pritelivir.
4. History of malignancy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2021
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-09-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-003639-27-NL
CCMO	NL78936.056.21

Study results